AUG - 5 2004

K041691

1 of 3

**Summary of Safety and Effectiveness for the Clip'n'Ject Reconstitution System**

**Submitted by**:

West Pharmaceutical Services, Inc.
101 Gordon Drive
Lionville, PA 19341

**Contact Person**

Please direct all inquiries regarding this submission to our official correspondent:

David Weiser
Supervisor, Regulatory Affairs, the Americas
101 Gordon Drive
Lionville, PA 19341

Telephone No.: (610) 594-2931
Facsimile No: (610) 594-3016

**Classification Name**: Fluid Transfer Set per 21 CFR § 880.5440

**Common/Usual Name:** Reconstitution system, administration system including a sliding joint and vial adapter

**Proprietary Name**: Clip'n'Ject™ Reconstitution System (Clip'n'Ject)

**Identification of a Legally Marketed Predicate Device**

West's Clip'n'Ject Reconstitution System is substantially equivalent to:

- Inter - Vial that is legally marketed and distributed by Duoject Medical Systems Inc. pursuant to premarket notification K010703
- Needle-Free Adapter that is legally marketed and distributed by Bioject, Inc. pursuant to pursuant to premarket notification K963012;
- Mixject that is legally marketed and distributed by Medimop Medical products Ltd. pursuant to premarket notification K963853.

**Device Description**

Clip'n'Ject Reconstitution System is a single use device intended to transfer, mix and inject lyophilized drugs contained in vials. The Clip'n'Ject Reconstitution System shown in Figure 1 is comprised of a sliding joint and connector and is compatible with a BD Readyfill or comparable syringe(s). The syringe and needle would be legally authorized through its own clearance or customer NDA and is not intended to be cleared as part of this premarket notification. The needle is attached to the syringe by means of a standard luer connection. The sliding joint is placed onto a portion of the syringe. The syringe with the sliding joint and needle is inserted into the connector.

K041109
2 of 3

The user attaches the Clip'n'Ject Reconstitution System to a vial by inserting the vial into the connector. The system is then activated by pressing down on the syringe. This advances the needle into the vial through the vial stopper. The user then attaches the plunger rod to the syringe. The contents of the syringe are then transferred into the vial. Mixing of the syringe contents and vial contents then occurs. After this is complete, the mixture is then drawn back into the syringe. The syringe with needle attached is then removed from the connector and sliding joint. The syringe can then be used for administration. This system is disposable and for single use only.

**Product Configurations**

The Clip'n'Ject Reconstitution System is available in three sizes to accommodate vials with 13 mm and 20 mm tops. The 20 mm version has two possible body diameters: 20.75 mm and 23.75 mm. The device for a 13 mm top vial will accommodate a 1 cc syringe; the device for the 20 mm top vial will accommodate a 3 cc syringe. Each size Clip'n'Ject Reconstitution System will be packaged with a customer specified diluent (e.g. Sterile water for injection (WFI).The matrix of configurations are shown in Table 1.

**Table 1: Clip'n'Ject Configurations**

| Vial Cap Diameter | 1 CC Syringe | 3 CC Syringe |
|---|---|---|
| Clip'n'Ject - 13 mm | ✓ | |
| Clip'n'Ject - 20 mm* | | ✓ |
| Clip'n'Ject - 23.75 mm† | | ✓ |

*To fit a vial with a 20 mm vial top diameter and a 20.75(nominal) vial body diameter
†To fit a vial with a 20 mm vial top diameter and a 23.75(nominal) vial body diameter

Table 1 shows the current configurations available. Other combinations are possible without changing the design parameters for the system. These would include a connector that would attach a 3 cc syringe to a 13 mm vial top and a connector that would attach a 1 cc syringe to a 20 mm vial top.

**Intended Use**

The Clip'n'Ject Reconstitution System is a single use device intended to transfer diluent into a vial containing a lyophilized drug, mix the diluent and the lyophilized drug, and transfer the reconstituted drug into a standard syringe. The Clip'n'Ject Reconstitution system may be used by physicians, nurses, and other practitioners who routinely administer injections, or by patients and other individuals authorized by their physician to administer injections of prescribed medication.

K041161
3 of 3

**Summary of Technological Characteristics**

A six (6) point comparison of technological characteristics of the West Pharmaceutical Services' Clip'n'Ject Reconstitution System and the predicate devices was performed. The devices were found to be substantially equivalent. The areas of comparison are: Intended use, sterilization method, packaging, vial size compatibility, piercing mechanism and housing material.

**Summary of Performance Data**

West Pharmaceutical Services' Clip'n'Ject Reconstitution System complies with the requirements of the following FDA Recognized Consensus Standards:

- ANSI/AAMI/ISO 11135-1995, *Guideline for Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*
- AAMI TIR 10:2000, *Process Development and Performance Qualification for Ethylene Oxide Sterilization – Microbiological Aspects*
- AAMI/ANSI/ISO: 10993-7:1995 ® 2001, *Biological Evaluation of Medical Devices – part 7: Ethylene Oxide Sterilization Residuals*

The West Clip'n'Ject Reconstitution System is substantially equivalent to:

- Inter - Vial that is legally marketed and distributed by Duoject Medical Systems Inc. (K010703);
- Needle-Free Adapter that is legally marketed and distributed by Bioject, Inc. (K963012);
- Mixject that is legally marketed and distributed by Medimop Medical Products Ltd. (K963583)

**Request for Confidentiality**

The information contained both in the body of this submission and marked as such is considered to be confidential within the meaning as set forth in 21 CFR Part 20.

JUN 21 2004

000013

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 5 2004

Mr. David J. Weiser
Supervisor, Regulatory Affairs, The Americas
West Pharmaceutical Services, Incorporated
Pharmaceutical Systems Division
101 Gordon Drive
Lionville, Pennsylvania 19341

Re: K041691
Trade/Device Name: Clip'n' Ject Reconstitution System
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: June 21, 2004
Received: June 22, 2004

Dear Mr. Weiser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

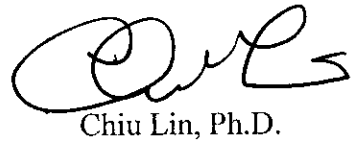
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K041691
1 of 1

# Indications for Use

510(k) Number (if known): K041691

Device Name: Clip'n'Ject Reconstitution System

Indications For Use:

The Clip'n'Ject Reconstitution System is a single use device intended to transfer diluent into a vial containing a lyophilized drug, mix the diluent and the lyophilized drug, and transfer the reconstituted drug into a standard syringe. The Clip'n'Ject Reconstitution System may be used by physicians, nurses, and other practitioners who routinely administer injections, or by patients and other individuals authorized by their physician to administer injections of prescribed medication.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041691